DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date 5-10-01
Publication Date 5-11-01
Certifier SReese

[Docket No. 01D–0177]

Draft Guidance for Industry on Immunotoxicology Evaluation of Investigational New Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Immunotoxicology Evaluation of Investigational New Drugs." This draft guidance provides recommendations for sponsors of investigational new drugs (INDs) on the parameters that should be routinely assessed in toxicology studies to determine effects on immune function, when additional specific immunotoxicity studies should be conducted, and when additional mechanistic information could better evaluate a given effect on the immune system.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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FOR FURTHER INFORMATION CONTACT: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5476.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Immunotoxicology Evaluation of Investigational New Drugs." The immune system consists of a diffuse and complex set of cells and organs that have complicated interactions with each other and with other physiological systems. These complexities make the detection and evaluation of drug-induced immunotoxicity in animal models difficult. Immunotoxicologic findings could suggest the need for additional followup studies, particularly if the observed adverse effects are serious. The objective of these followup studies would be to investigate the nature and mechanism of the immunotoxic effects. Immunotoxicity findings could lead to modifications in proposed clinical trials or could be included in the investigator's brochure or product label. Rarely, immunotoxicity findings could indicate that a drug is unsafe for some types of clinical investigations or certain indications.

For the safety assessment of INDs, specific immunotoxicity testing should be conducted when drugs are to be administered by inhalation or topically. Specific immunotoxicity studies should also be considered for safety assessment purposes when: (1) The drug has the potential to elicit an anti-drug immune response; (2) use of the drug during pregnancy is likely; (3) there is an absence of immunotoxicity findings in the toxicology studies, but there is significant accumulation or retention of the drug in immune system tissues; or (4) the drug will be used to treat an immune-deficiency disease such as the human immunodeficiency virus (HIV). In most other instances, specific immunotoxicity studies are generally not needed to support initial clinical trials or continued development.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on immunotoxicology evaluation of INDs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 5/4/01
May 4, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S